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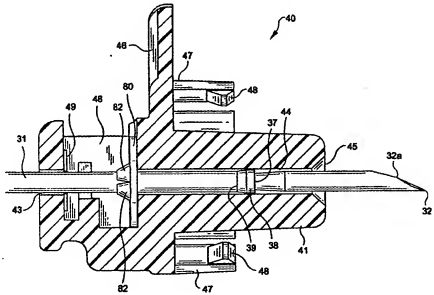


(57) Abstract

A catheter and introducer needle assembly with needle shield is provided wherein the needle includes an enlarged diameter portion and a distally facing shoulder. The needle shield includes a means for engaging the distally facing shoulder to prevent unwanted distal movement of the needle once the needle has been withdrawn into the needle shield. The needle shield also includes a small diameter opening adjacent to its proximal portion to limit proximal movement of the needle out of the needle shield.

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# CATHETER AND INTRODUCER NEEDLE ASSEMBLY WITH NEEDLE SHIELD

This application is a continuation-in-part of application Serial No. 09/057,718 filed April 9, 1998

## Background of the Invention

The subject invention relates to a catheter and introducer needle assembly that includes a needle shield that will safely shield the sharp distal tip of the introducer needle after the needle has been used to insert the catheter into a patient.

Catheters, particularly intravenous (IV) catheters, are used for infusing fluid, such as normal saline solution, various medicaments and total parenteral nutrition, into a patient or withdrawing blood from a patient. Peripheral IV catheters tend to be relatively short, and typically are on the order of about two inches or less in length. The most common type of IV catheter is an over the needle peripheral IV catheter. As its name implies, an over the needle catheter is mounted over an introducer needle having a sharp distal tip. The catheter and the introducer needle are assembled so that the distal tip of the introducer needle extends beyond the distal tip of the catheter with the bevel of the needle facing up away from the patient's skin.

The catheter and introducer needle assembly is inserted at a shallow angle through the patient's skin into a peripheral blood vessel, i.e a smaller blood vessel that is not connected directly to the heart but is one of the branches of the central blood vessels that is directly connected to the heart. In one technique, the introducer needle and catheter are inserted completely into the blood vessel together. In another technique, the introducer needle is partially withdrawn into the catheter after the initial venipuncture. The catheter

is then inserted completely into the blood vessel. In order to verify proper placement of the assembly in the blood vessel, the clinician confirms that there is flashback of blood in the needle and in a flashback chamber located at the proximal end of the needle and which is typically formed as part of the needle hub. Once proper placement is confirmed, the clinician applies pressure to the blood vessel by pressing down on the patient's skin over the distal tip of the introducer needle and the catheter. This finger pressure occludes further blood flow through the introducer needle. The clinician withdraws the introducer needle, leaving the catheter in place, and attaches a fluid delivery device, a PRN or a deadender cap to the catheter hub. Once the introducer needle is withdrawn from the catheter, it is a "blood contaminated sharp" and must be properly handled.

In recent years, there has been great concern over the contamination of clinicians with a patient's blood and a recognition that "blood contaminated sharps" must be immediately disposed. This concern has arisen because of the advent of currently incurable and fatal diseases, such as Acquired Immunosuppressive Deficiency Syndrome ("AIDS"), which can be transmitted by the exchange of body fluids from an infected person to another person. Thus, contact with the body fluid of an AIDS infected person must be avoided. As noted above, if an introducer needle has been used to place a catheter in the vein of an AIDS infected person, the introducer needle is a vehicle for the transmission of the disease. Although clinicians are aware of the need to properly handle "blood contaminated sharps", unfortunately in certain medical environments, such as emergency situations or as a result of inattention or neglect, needlesticks with a contaminated introducer needle still occur.

As a result of the problem of accidental needlesticks by "blood contaminated sharps", various needle shields have been developed. Generally, such needle shields work for their intended purpose but could be improved. For example, some needle shields are bulky, difficult to use or require special features or techniques to be operative.

Summary of the Invention

It is therefore an object of this invention to provide a needle shield that is compact.

It is another object of this invention to provide a needle shield that is simple and easy to use.

It is still another object of this invention to provide a needle shield that requires no special features or technique to be operative.

The catheter and introducer needle assembly with needle shield of this invention includes a catheter having a distal end and a proximal end connected to the distal end of a catheter hub. The introducer needle has a sharp distal tip and a proximal end connected to the distal end of a needle hub. A flashback chamber is defined in the needle hub. Typically a porous plug is located in the open proximal end of the flashback chamber to allow air to escape from the flashback chamber when blood enters the flashback chamber from the introducer needle. The catheter is coaxially disposed over the introducer needle so the sharp distal tip of the introducer needle is distal of the distal end of the catheter. The introducer needle also defines, along a distal portion thereof, an enlarged diameter portion with a distally facing shoulder immediately distal thereof and a tapered portion immediately proximal thereof. The enlarged diameter portion cooperates with a needle shield to prevent unwanted proximal movement of the introducer needle with respect to the needle shield once the introducer needle has been withdrawn into the needle shield after use. The distally facing shoulder cooperates with the needle shield to prevent unwanted distal movement of the introducer needle once the introducer needle has been withdrawn proximally into the needle shield after use.

The needle shield includes a main body portion defining a longitudinally extending passage through which the introducer needle extends. The needle shield also includes a means for engaging the distally facing shoulder of the

introducer needle to prevent distal movement of the introducer needle once the introducer needle has been proximally withdrawn into the needle shield. The longitudinally extending passage has a proximal portion that has a diameter sufficient to allow the proximal portion of the introducer needle to extend therethrough but that is too small to allow the enlarged diameter portion of the introducer needle from passing therethrough.

The means for engaging the distally facing shoulder of the introducer needle can take many forms. For example, a spring gate can be located in a hollow cavity portion of the main body portion of the needle shield and about a portion of the introducer needle. The spring gate has a generally U shaped configuration with a pair of tines that allow the introducer needle to pass between the tines. A biasing mechanism forces the spring gate up into contact with the introducer needle. When the introducer needle is withdrawn proximally into the needle shield, the introducer needle rides past the tines. When the enlarged diameter portion passes by the tines, the spring gate is forced downwardly against the bias of the biasing mechanism to allow the enlarged diameter portion of the introducer needle to pass proximally past the spring gate. The proximal movement of the introducer needle into the needle shield is facilitated by a tapered portion of the introducer needle immediately proximal of the enlarged diameter portion that ensures a smooth transition from the proximal portion of the introducer needle to the enlarged diameter portion. Once the distally facing shoulder is proximal of the spring gate, the biasing mechanism forces the spring gate into engagement with the shaft of the introducer needle. This ensures that the introducer needle engages the spring gate so the tines extend up past the introducer needle. If a clinician then tried to advance the introducer needle distally, the distally facing shoulder would butt up against the spring gate which in turn would butt up against the distal wall of the cavity in the main body portion and prevent the introducer needle from being moved distally. Thus the sharp distal tip of the introducer

needle would be prevented from being reexposed distally from the needle shield.

A variation of the spring gate discussed above is a leaf spring. The leaf spring has a proximal wall, a support leg and a locking leg. The support leg and the locking leg are configured into a generally V-shape, with the apex of the V facing distally. The locking leg is contoured to approximate a portion of the circumference of the introducer needle and rides along the introducer needle shaft. The configuration of the leaf spring ensures that the locking leg is biased toward the introducer needle but can be moved down away from the introducer needle so that the locking leg can ride over the enlarged diameter portion as the introducer needle is moved proximally into the needle shield. Once the distally facing shoulder is moved proximally of the proximal end of the locking leg of the leaf spring, the locking leg moves back into contact with the shaft of the introducer needle. If the introducer needle is moved distally, the proximal end of the locking leg of the leaf spring will engage the distally facing shoulder and prevent further distal movement of the introducer needle.

An alternative means for engaging the distally facing shoulder is a tube formed in the main body portion. The tube is coaxially located in the longitudinal passage of the main body portion and includes at least one movable lanced protrusion or tab that extends inwardly into the tube. Because the tab is movable, the distally facing shoulder can move proximally past the tab. Once the introducer needle has been withdrawn proximally into the needle shield such that the tab is distal of the distally facing shoulder, any distal movement of the introducer needle will be prevented when the distally facing shoulder engages the tab.

Yet another means for engaging the distally facing shoulder is a disk that is formed in or added to the main body portion. The disk is coaxially located in the longitudinal passage of the main body portion and defines a through hole and at least one proximally oriented, inwardly extending tab adjacent the through hole. The tab is also preferably oriented at an angle less

than 90 degrees to the introducer needle. The through hole should be slightly larger than the diameter of the introducer needle to allow the major portion of the introducer needle to pass therethrough. Because the tab is movable, the distally facing shoulder can move proximally past the tab. Once the introducer needle has been withdrawn proximally into the needle shield such that the tab is distal of the distally facing shoulder, any distal movement of the introducer needle will be prevented when the distally facing shoulder engages the tab. In addition, since the tab is proximally oriented at an angle less than 90 degrees to the introducer needle, additional force would be required to allow the introducer needle to be subsequently moved distally. And in certain instances a distally facing shoulder may not be necessary as long as the tab engages the surface of the introducer needle if it is moved distally.

The distal portion of the needle shield includes a plurality of longitudinally extending fingers and radially inwardly extending projections that engage the proximal end of the catheter hub. This ensures that the needle shield remains engaged with the catheter until the introducer needle has been completely removed from the catheter and is safely shielded in the needle shield.

Brief Description of the Drawings

The preferred embodiments are illustrated in the drawings in which like reference numerals refer to like elements and in which:

FIG. 1 is a perspective view of the catheter and introducer needle assembly with the needle shield of this invention;

FIG. 2 is an enlarged elevation view, partially in cross-section, of the distal portion of the introducer needle used in the catheter and introducer needle assembly with the needle shield of this invention;

FIG. 3 is a cross-sectional view of a first embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle extending from the distal end of the needle shield;

FIG. 4 is a cross-sectional view of the first embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle withdrawn into the needle shield;

FIG. 5 is a cross-sectional view of the first embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle locked in the needle shield in its distal most position;

FIG. 6 is a perspective view of the spring gate that is used in the embodiment of FIGS. 3 through 5 to lock the introducer needle in the needle shield;

FIG. 7 is a perspective cross-sectional view of a second embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle extending from the distal end of the needle shield;

FIG. 8 is a cross-sectional view of the second embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle locked in the needle shield;

FIG. 9 is a perspective view of the leaf spring that is used in the embodiment of FIGS. 7 and 8 to lock the introducer needle in the needle shield;

FIG. 10 is a cross-sectional view of a third embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle extending from the distal end of the needle shield;

FIG. 11 is a cross-sectional view of the third embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle locked in the needle shield;

FIG. 12 is a perspective cross-sectional view of the tube that is used in the embodiment of FIGS. 10 and 11 to lock the introducer needle in the needle shield;

FIG. 13 is a cross-sectional view of a fourth embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle extending from the distal end of in the needle shield;

FIG. 14 is a cross-sectional view of the fourth embodiment of the needle shield and the distal portion of the introducer needle with the sharp distal tip of the introducer needle locked in the needle shield; and

FIG. 15 is a perspective cross-sectional view of the disk that is used in the embodiment of FIGS. 13 and 14 to lock the introducer needle in the needle shield.

Detailed Description of the Invention

As used herein, the term "proximal" refers to a location on the catheter and introducer needle assembly with the needle shield of this invention closest to the clinician using the device and farthest from the patient in connection with whom the device is used. Conversely, the term "distal" refers to a location on the catheter and introducer needle assembly of this invention farthest from the clinician using the device and closest to the patient in connection with whom the device is used.

Although this invention is described herein in connection with a typical peripheral IV catheter, it is to be understood that this invention is applicable to other catheters such as catheters with extension tubes and extended dwell catheters requiring the needle to be connected to the needle hub by a stylet as well as other medical devices where it is desirable for a needle to be shielded after use. In addition, while this invention is satisfied by embodiments in many different forms, there are shown in the drawings and herein described in detail, preferred embodiments of the invention with the scope of the invention measured by the appended claims.

The catheter and introducer needle assembly of this invention is identified generally by the numeral 10. It includes a catheter assembly 20 and an introducer needle assembly 30 that includes a needle shield 40.

Catheter assembly 20 includes a catheter 21 that has a proximal end 22, a distal end 23 and a catheter hub 24 affixed to catheter proximal end 22. Suitable materials for catheter 21 include, but are not limited to, thermoplastic resins such as polytetrafluoroethylene (PTFE), polyurethane and the like. Preferably, catheter 21 is formed from a thermoplastic hydrophilic polyurethane that softens with exposure to physiological conditions present in the patient's body. Suitable materials for catheter hub 24 include, but are not limited to, thermoplastic polymeric resins such as polycarbonate, polystyrene, polypropylene and the like. Catheter hub 24 may include a radially outwardly extending tab, not shown, which is useful for advancing catheter 21 into the patient's blood vessel.

Introducer needle assembly 30 includes introducer needle 31 having a sharp distal tip 32 defined by bevel 32a and a proximal end 33 connected to needle hub 34. Introducer needle 31 is preferably formed from stainless steel. Needle hub 34 can include an integrated flashback chamber having an open proximal end 35. Needle hub 34 is preferably formed from the same types of materials that are used to form catheter hub 24. Preferably, open proximal end 35 is closed to fluid flow by a porous plug 36 which allows air but not fluid to flow therethrough.

Introducer needle assembly 30 also includes needle shield 40 which includes main body portion 41 and which in turn defines a longitudinally extending passage 42 having a proximal portion 43, a distal portion 44 and a distal opening 45. This allows introducer needle 31 to extend longitudinally through main body portion 41. The diameter of proximal portion 43, distal portion 44 and distal opening 45 is slightly larger than the diameter of the main portion of introducer needle 31. This allows the main portion of introducer needle 31 to easily pass through proximal portion 43, distal portion 44 and distal opening 45. Main body portion 41 also includes a radially extending flange 46 and a plurality of longitudinally extending fingers 47. Fingers 47 also include radially inwardly directed projections 48. Fingers 47 and projections

48 engage catheter hub 24 to hold introducer needle assembly 30 together with catheter assembly 20.

Introducer needle 31 includes a distally facing shoulder 37, an enlarged diameter portion 38 and a tapered proximal portion 39. See FIG. 2. Preferably, distally facing shoulder 37, enlarged diameter portion 38 and tapered proximal portion 39 are formed on introducer needle 31 by centerless grinding a larger diameter introducer needle. Enlarged diameter portion 38 should have a diameter greater than the diameter of proximal portion 43. This ensures that introducer needle 31 cannot be pulled in a proximal direction completely out of needle shield 40 because enlarged diameter portion 38 blocks further movement of introducer needle 31 through proximal portion 43. Alternatively, a washer 49 having an opening therein with a diameter smaller than the diameter of enlarged diameter portion 38 can be placed over the distal opening to proximal portion 43 of longitudinally extending passage 42 to prevent enlarged diameter portion 38 from passing into proximal portion 43.

The annulus formed by distally facing shoulder 37 against the shaft of introducer needle 31 should have a diameter of at least about 0.002 inches. It has been surprisingly found that this dimension is sufficient, when used in conjunction with needle shield 40 of this invention, to prevent introducer needle 31 from being moved distally out of needle shield 40 after introducer needle 31 has been withdrawn proximally into needle shield 40 to lock sharp distal tip 32 in needle shield 40. To ensure a sufficiently large diameter for the annulus of distally facing shoulder 37, that portion of introducer needle 31 immediately distal to distally facing shoulder 37 can be formed with a slightly increasing taper from distally facing shoulder 37 toward the distal end of introducer needle 31. This taper can be formed by grinding that portion of introducer needle 31 immediately distal of distally facing shoulder 37.

The means for engaging distally facing shoulder 37 of introducer needle 31 can take many forms. For example, as shown in FIGS. 3 through 6, a spring gate 50 can be used to lock introducer needle 31 in place in needle

shield 40. Spring gate 50 is located in a hollow cavity portion 48 of main body portion 41 of needle shield 40 and about introducer needle 31. Spring gate 50 has a generally U shape with a pair of tines 51 that allow introducer needle 31 to pass through spring gate 50 between tines 51. The distance between times 51 is slightly larger than the diameter of the main portion of introducer needle 31 and is less than the diameter of enlarged diameter portion 38. A biasing mechanism 55 forces spring gate 50 up into contact with introducer needle 31 and ensures that spring gate 50 remains engaged with introducer needle 31. Biasing mechanism 55 may take any appropriate form. For example, it may be a helical spring as shown in the FIGS. or it may be a compressible rubber-like material that acts as a spring. Spring gate 50 also includes a seat 52 that extends generally perpendicular to tines 51 to ensure that spring gate 50 maintains contact with biasing mechanism 55 and remains in proper position.

When introducer needle 31 is withdrawn proximally into needle shield 40, introducer needle 31 rides past tines 51. As tapered proximal portion 39 passes by tines 51, spring gate 50 is forced downwardly against the bias of biasing mechanism 55 to allow enlarged diameter portion 38 to pass proximally past spring gate 50. Once enlarged diameter portion 38 is proximal of spring gate 50, biasing mechanism 55 forces spring gate back into engagement with introducer needle 31. When enlarged diameter portion 38 is proximal of spring gate 50, sharp distal tip 32 defined by bevel 32a is proximal of distal opening 45 and is thus safely located in needle shield 40. Distal movement of introducer needle 31 is prevented because distally facing shoulder 37 engages tines 51 which in turn engage the distal wall of cavity 48 to prevent distal movement of enlarged portion 38 into distal portion 44 of longitudinally extending passage 42. Thus, if a clinician then tried to advance introducer needle 31 distally, biasing mechanism 55 would ensure that spring gate 50 is in contact with the distal portion of the shaft of introducer needle 31 and distally facing shoulder 37 would butt up against spring gate 50 which in turn would butt up against the distal wall of cavity 48. This would prevent

introducer needle 31 from being moved distally and thus prevent sharp distal tip 32 of introducer needle 31 from being reexposed from needle shield 40. And as discussed above, further proximal movement of introducer needle 31 from needle shield 40 is prevented because enlarged diameter portion 38 blocks further proximal movement of introducer needle 31 through proximal portion 43.

A variation of spring gate 50 discussed above is to use a leaf spring 60. See FIGS. 7 through 9. Leaf spring 60 has a proximal wall 61 defining an opening 62 therein aligned with proximal portion 43 of longitudinally extending passage 42. Proximal wall 61 is generally perpendicular to the longitudinal axis of needle shield 40. Preferably the diameter of opening 62 is slightly larger than the diameter of the shaft of introducer needle 31 but smaller than the diameter of enlarged diameter portion 38. Leaf spring 60 also has a support leg 63 and a locking leg 64 which are configured into a generally V-shape lying on its side, with the apex of the V facing distally. This V-shaped configuration ensures that locking leg 64 is biased toward introducer needle 31. Locking leg 64 is contoured along its proximal portion to form a generally semi-circular cross-section to approximate a portion of the circumference of introducer needle 31.

Locking leg 64 rides along the shaft of introducer needle 31 as introducer needle 31 is withdrawn proximally into needle shield 40. Locking leg 64 rides over tapered proximal portion 39 and enlarged diameter portion 38 as introducer needle 31 continues to be withdrawn into needle shield 40. Tapered proximal portion 39 facilitates movement of enlarged diameter portion 38 past locking leg 64. Once enlarged diameter portion 38 and distally facing shoulder 37 are moved proximally of the proximal end of locking leg 64, locking leg 64 moves back into contact with the shaft of introducer needle 31. If introducer needle 31 is moved distally, the proximal end of locking leg 64 will engage distally facing shoulder 37 and prevent further distal movement of introducer needle 31. Further proximal movement of introducer needle 31 is

prevented by the engagement of enlarged diameter portion 38 with proximal wall 61.

Another alternative means for engaging distally facing shoulder 37 is a tube 70 located in needle shield 40. See FIGS. 10 through 12. Tube 70 is coaxially located in longitudinally extending passage 42 and includes at least one movable lanced tab 71 that extends inwardly into tube 70 in a proximal direction. Preferably two such tabs 71 are formed on opposite sides of tube 70. Because tabs 71 are movable, tapered proximal portion 39 and enlarged diameter portion 38 can move past the proximal ends of tabs 71 as introducer needle 31 is withdrawn proximally into needle shield 40. Again the proximal movement of introducer needle 31 is facilitated by proximal tapered portion 39. Once introducer needle 31 has been withdrawn proximally into needle shield 40 such that tabs 71 are distal of distally facing shoulder 37, any distal movement of introducer needle 31 will be prevented by the engagement of the proximal ends of tabs 71 with distally facing shoulder 37. Further proximal movement of introducer needle 31 is prevented by the engagement of enlarged diameter portion 38 with proximal portion 43.

Yet another alternative means for engaging distally facing shoulder 37 is a disk 80 located in needle shield 40. See FIGS. 13 through 15. Disk 80 is located in cavity 48 of main body portion 41 of needle shield 40 and about introducer needle 31. Disk 80 defines a through hole 81 that has a diameter slightly larger than the diameter of introducer needle 31. This allows introducer needle 31 to freely pass through disk 80. Disk 80 also includes at least one but preferably a plurality of movable tabs 82 that are proximally oriented and extend inwardly toward the proximal end of introducer needle 31. The ends of tabs 82 define the circumference of through hole 81. Preferably tabs 82 are oriented at an angle less than 90 degrees with respect to introducer needle 31 as seen in FIGS. 13 through 15. Because tabs 82 are proximally oriented and movable, tapered proximal portion 39 and enlarged diameter portion 38 can move easily past the proximal ends of tabs 82 as

introducer needle 31 is withdrawn proximally into needle shield 40. Again the proximal movement of introducer needle 31 is facilitated by proximal tapered portion 39. Once introducer needle 31 has been withdrawn proximally into needle shield 40 such that tabs 82 are distal of distally facing shoulder 37, any distal movement of introducer needle 31 will be prevented by the engagement of the proximal ends of tabs 82 with distally facing shoulder 37. Further proximal movement of introducer needle 31 is prevented by the engagement of enlarged diameter portion 38 with proximal portion 43 or washer 49.

The generally proximal orientation of tabs 82 prevents unwanted distal movement of introducer needle 31. In addition, this orientation increases the force that would have to be applied to introducer needle 31 if a clinician were to attempt to reexpose sharp distal tip 31 after it had been withdrawn into main body portion 41. Moreover, distally facing shoulder 37 may not be required in certain circumstances as long as tabs 82 are proximally oriented and engage the surface of introducer needle 31. This is because tabs 82 would tend to bite into the surface of introducer needle 31 and hold introducer needle 31 in place if a clinician attempted to move introducer needle 31 distally.

In order to place catheter 21 into a patient's blood vessel, the clinician substantially longitudinally aligns introducer needle 31 and catheter 21 with the target blood vessel. Bevel 32a should be facing substantially away from the skin surface during venipuncture. The clinician inserts introducer needle 31 and catheter 21 at a shallow angle, preferably less than about 35 degrees, into the skin so that sharp distal tip 32 enters the target blood vessel. The clinician then preferably observes a blood flashback in the flashback chamber of needle hub 34.

After confirming placement of introducer needle 31 and catheter 21 in the target blood vessel, the clinician advances catheter 21 distally axially along introducer needle 31 into position in the blood vessel. In certain techniques, introducer needle 31 may be partially withdrawn into catheter 21 before catheter 21 is completely advanced into position in the blood vessel. After

proper placement of catheter 21 is achieved, the clinician places a finger from her other hand on the patient's skin over the blood vessel approximately over distal end of catheter 21. By placing her finger on the patient's skin and applying sufficient pressure on the skin, the clinican thereby substantially occludes blood flow through catheter 21. The clinican then withdraws introducer needle 31 completely from catheter 21 by moving needle hub 34 proximally. This movement causes introducer needle 31 to move proximally into needle shield 40. However, fingers 47 and projections 48 cause needle shield to remain engaged with catheter hub 24 during at least the initial proximal movement of introducer needle 31. Continued proximally directed force applied to needle hub 34 causes fingers 47 and projections 48 to become disengaged from catheter hub 24 once sharp distal tip 32 is located in needle shield 40 and introducer needle 31 is locked therein by one of the embodiments described above. After introducer needle 31 and needle shield 40 have been removed from catheter hub 24, the clinician may then attach a fluid delivery device, a PRN or a deadender cap to catheter hub 24 and commence the planned treatment. Introducer needle 31 and needle shield 40 may then be disposed of according to the facility's disposal protocol.

Thus, it is seen that a catheter and introducer needle assembly with needle shield is provided that is compact, simple and easy to use and that requires no special features or technique to be operative.

We Claim:

1. A catheter and introducer needle assembly, comprising:

a catheter having a proximal end and distal end;

a catheter hub in fluid communication with the catheter and having a proximal end and a distal end connected to the proximal end of the catheter;

an introducer needle disposed in the catheter and having a proximal end and a distal end and defining an enlarged diameter portion and a distally facing shoulder;

a needle shield having a proximal end and a distal end removably connected to the catheter hub, the needle shield defining a longitudinally extending passageway therethrough with the introducer needle extending through the longitudinally extending passageway wherein the longitudinally extending passageway has a means for engaging the enlarged diameter portion of the introducer needle to prevent unwanted proximal movement of the introducer needle and wherein the needle shield includes a means for engaging the distally facing shoulder to prevent unwanted distal movement of the introducer needle.

2. The catheter and introducer needle assembly of claim 1 wherein the means for engaging the enlarged diameter portion of the introducer needle to prevent unwanted distal movement of the introducer needle is a disk with at least one proximally oriented, inwardly directed tab.

3. A needle shield assembly, comprising:

a needle having a proximal end and a distal end and defining an enlarged diameter portion and a distally facing shoulder; and

a needle shield movable along the needle.

4. A catheter and introducer needle assembly, comprising:

a needle having an enlarged diameter portion and a distally facing shoulder and a proximal end and a distal end;

a needle shield movable along the needle and having a proximal end and a distal end;

a latch operatively connected to the needle shield and slidable along the needle so as to be proximal of the enlarged diameter portion when the distal end of the needle is distal of the distal end of the needle shield and distal of the enlarged diameter portion to allow the latch to engage the distally facing shoulder after the distal end of the needle is withdrawn into the needle shield;

a catheter disposed about the needle; and

a catheter hub connected to the catheter wherein the needle shield is removably connected to the needle shield.

5. The catheter and introducer needle assembly of claim 4 wherein the latch has a generally U shaped gate and a biasing mechanism to bias the U shaped gate toward the introducer needle.

6. The catheter and introducer needle assembly of claim 4 wherein the latch is a tube defining at least one inwardly directed tab.

7. The catheter and introducer needle assembly of claim 4 wherein the latch is a leaf spring having one leg biased toward the introducer needle for engagement with the distally facing shoulder.

8. The catheter and introducer needle assembly of claim 4 wherein the latch is a disk having at least one proximally oriented, inwardly directed tab.

9. A catheter and introducer needle assembly, comprising:

a catheter having a proximal end and distal end;

a catheter hub in fluid communication with the catheter and having a proximal end and a distal end connected to the proximal end of the catheter;

an introducer needle disposed in the catheter;

a needle shield having a proximal end and a distal end removably connected to the catheter hub, the needle shield defining a longitudinally extending passageway therethrough with the introducer needle extending through the longitudinally extending passageway wherein the longitudinally extending passageway has a means for engaging the introducer needle to prevent unwanted distal movement of the introducer needle.

10. The catheter and introducer needle assembly of claim 9 wherein the means for engaging the introducer needle to prevent unwanted distal movement of the introducer needle is a disk with at least one proximally oriented, inwardly directed tab.

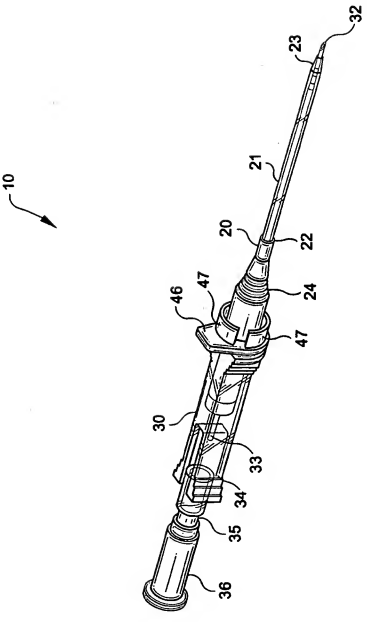


FIG-1

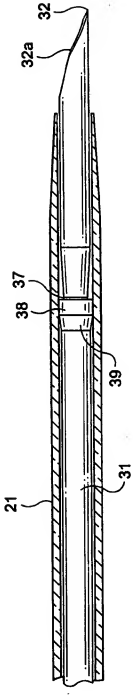


FIG-2

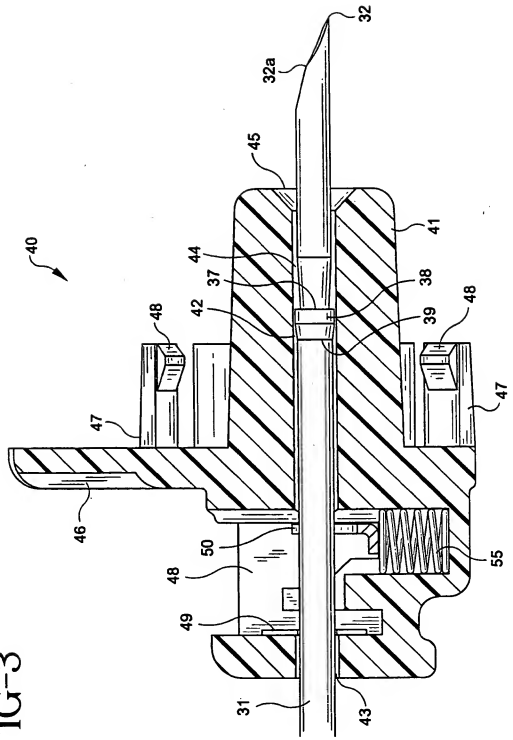


FIG-3

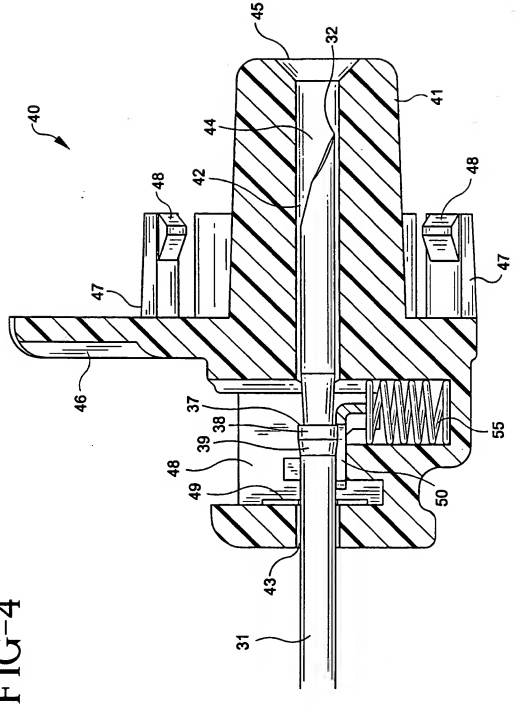


FIG-4

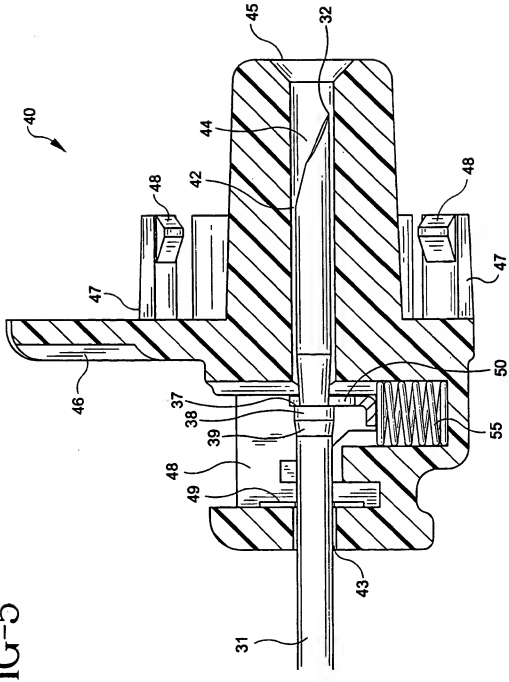


FIG-5

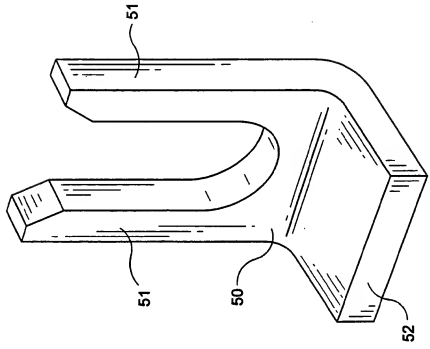


FIG-6

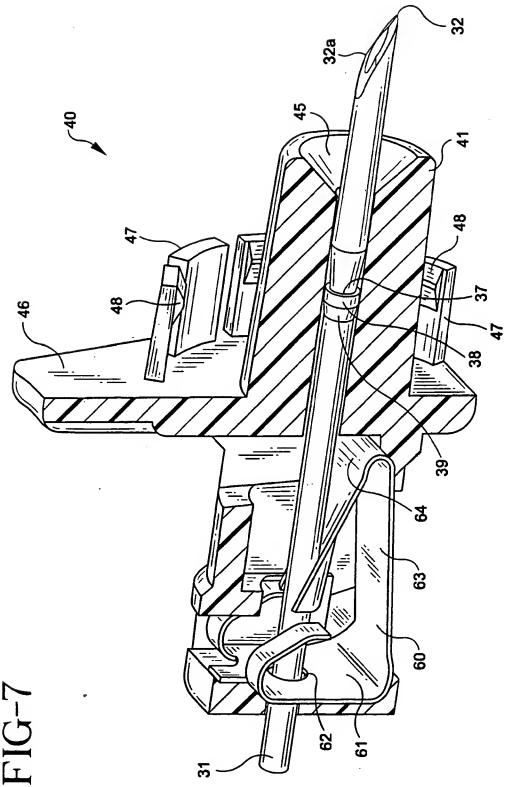


FIG-7

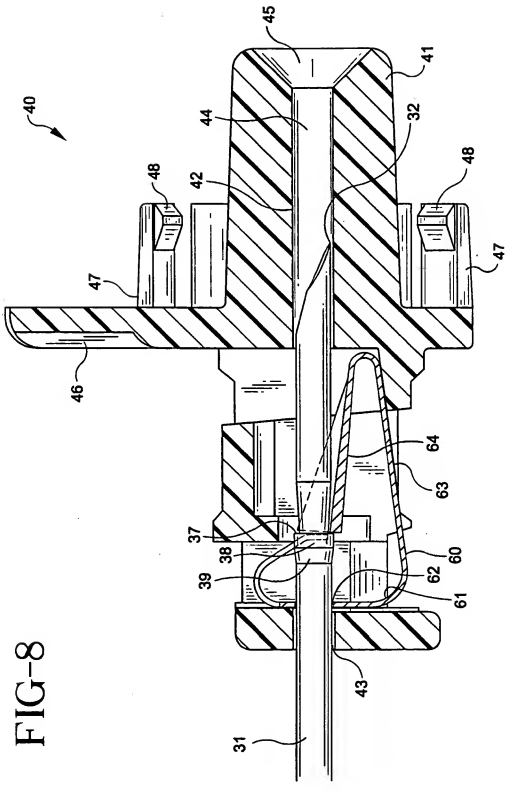


FIG-8

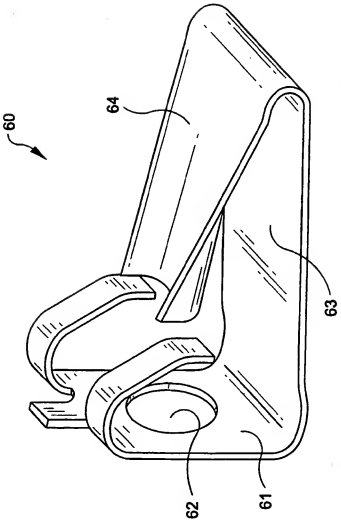


FIG-9

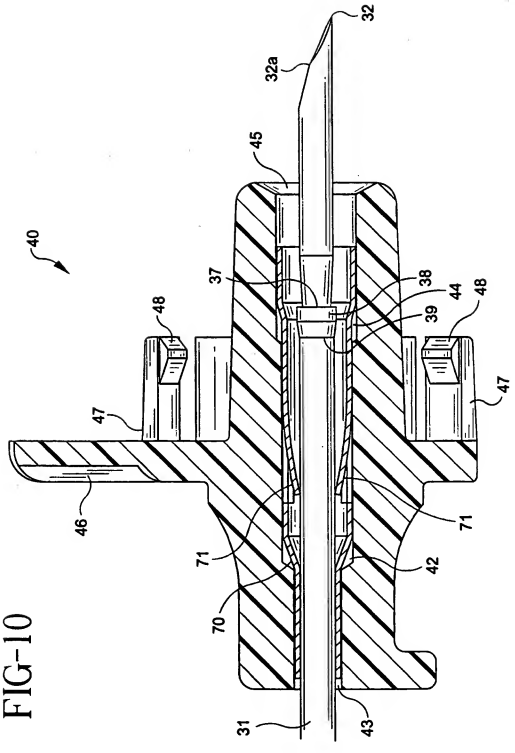


FIG-10

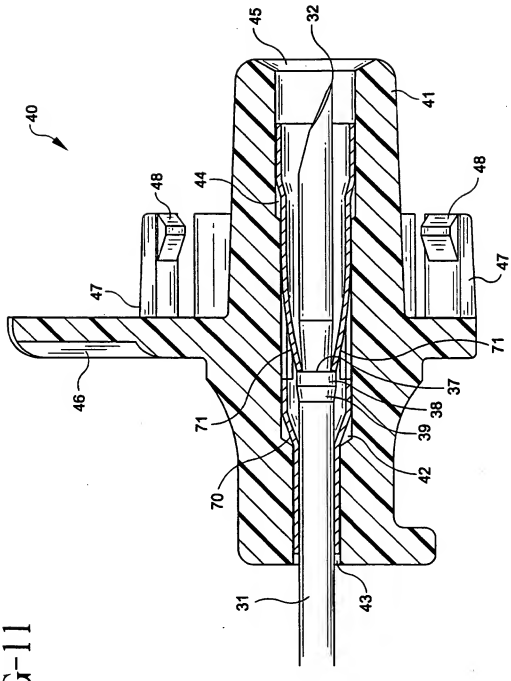


FIG-11

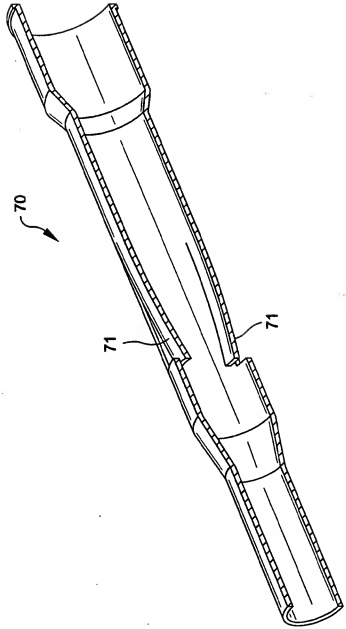


FIG-12

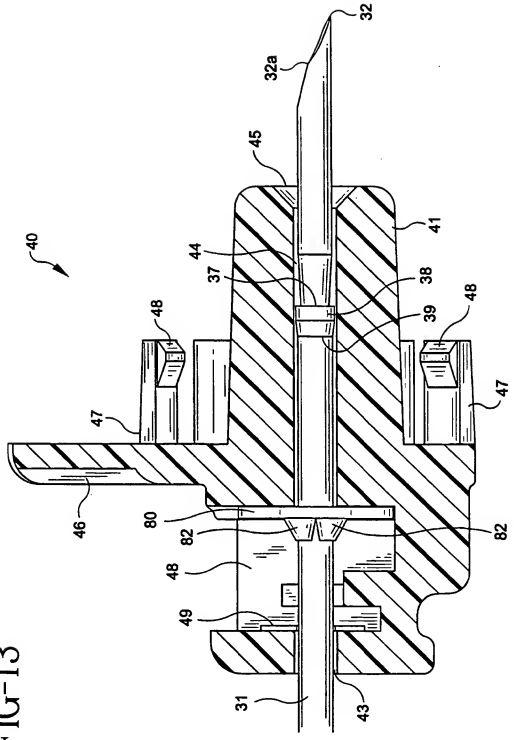


FIG-13

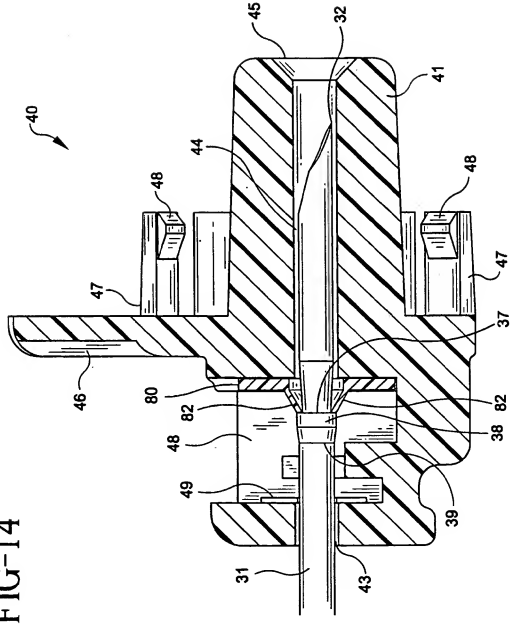


FIG-14

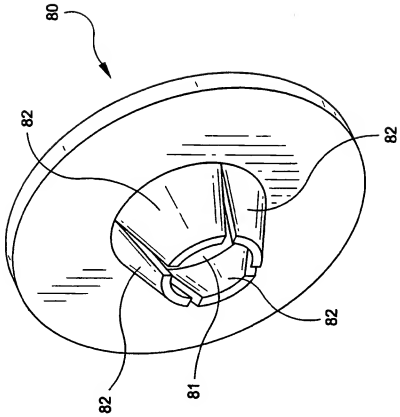


FIG-15

# INTERNATIONAL SEARCH REPORT

Intern. nal Application No
PCT/US 99/20540

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/06 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 14 March 2000 | 21/03/2000 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Michels, N |

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